Message

From: Teter, Royan [Teter.Royan@epa.gov]
Sent: 7/20/2018 1:39:29 PM
To: Kelley, Rosemarie [Kelley.Rosemarie@epa.gov]
CC: Sullivan, Greg [Sullivan.Greg@epa.gov]; Werner, Jacqueline [Werner.Jacqueline@epa.gov]
Subject: RE: Importance of the GLP Audit and Inspection Program- Please pause

Thanks Rosemarie. I can appreciate David's concern. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Our first involvement was an outgrowth of the meeting Susan had with CLA a few weeks ago. While the major focus of that meeting was the FIFRA ERP, they took advantage of the opportunity to raise several other issues, including the GLP concerns outlined in their recent email. Recognizing, there have been fewer GLP enforcement cases in recent years, we sought some feedback from OPP to inform a decision on whether we need to place more emphasis on pursuing cases when they arise. Shortly after the meeting, Tom and Brian reached out to Denise Rice, OPP's Director of Quality Assurance to explore the validity of CLA's claims. Based on the feedback they received, we didn't pursue it any further at that time.

When the email arrived, Greg shared it with me. I asked if we needed to pitch in with crafting a response in light of our earlier research. Greg noted we'd not been tasked with responding, but thought it made sense to check in with OPP for a more formal read on where they are with the GLP Program. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Lance is out this week. In his absence, I reached out to Yvette Hopkins for help with identifying the people in OPP who could provide a more robust OPP perspective on the GLP Program. She agreed to help, but later noticed CLA's email was also address to OSCPP's senior leadership team which prompted her to check in with Jackie Mosby before proceeding. Jackie, in turn, reached out to OC to initiate some coordination across the offices. That led to Liz shooting out a note asking to be brought up to speed ahead of a GLP briefing OC is doing for Susan on Monday. I shot her a short summary and offered to fill in the gaps by phone.

I think this covers the history up to this morning's' email traffic. I hope this is helpful. I'll let Yvette know she can stand down on our request.

Royan

From: Kelley, Rosemarie
Sent: Friday, July 20, 2018 8:08 AM
To: Hindin, David <Hindin.David@epa.gov>
Cc: Sullivan, Greg <Sullivan.Greg@epa.gov>; Segall, Martha <Segall.Martha@epa.gov>; Dombrowski, John <Dombrowski.John@epa.gov>; Teter, Royan <Teter.Royan@epa.gov>
Subject: Re: Importance of the GLP Audit and Inspection Program- Please pause

Ex. 5 Deliberative Process (DP)

Rosemarie

On Jul 20, 2018, at 8:04 AM, Hindin, David <Hindin.David@epa.gov> wrote:

Rosemarie:

Ex. 5 Deliberative Process (DP)

David A. Hindin
Director, Office of Compliance
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency, Washington, DC 20460
Phone 202-564-1300

From: Hindin, David
Sent: Friday, July 20, 2018 8:03 AM
To: Bodine, Susan <bodine.susan@epa.gov>
Cc: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>; sullivan.greg@epa.gov; Traylor, Patrick <traylor.patrick@epa.gov>; John Dombrowski (Dombrowski.John@epa.gov) <Dombrowski.John@epa.gov>; Segall, Martha <segall.martha@epa.gov>; Duffy, Rick <Duffy.Rick@epa.gov>; Liz Vizard (Vizard.Elizabeth@epa.gov) <Vizard.Elizabeth@epa.gov>
Subject: Importance of the GLP Audit and Inspection Program- Please pause
Importance: High

Susan:

The GLP Program is run by the Office of Compliance. We are briefing you on the program and key issues on Monday. This email raises substantive, organizational, and historical issues, and now a possible HR personnel issue. **Ex. 5 Deliberative Process (DP)**

David A. Hindin
Director, Office of Compliance
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency, Washington, DC 20460
Phone 202-564-1300

From: Bodine, Susan
Sent: Thursday, July 19, 2018 12:07 PM
To: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>
Cc: Starfield, Lawrence <Starfield.Lawrence@epa.gov>; Traylor, Patrick <traylor.patrick@epa.gov>
Subject: FW: Importance of the GLP Audit and Inspection Program

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Thursday, July 19, 2018 9:49 AM
To: Bodine, Susan <bodine.susan@epa.gov>
Cc: Starfield, Lawrence <Starfield.Lawrence@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Keigwin, Richard

<Keigwin.Richard@epa.gov>; Messina, Edward
<Messina.Edward@epa.gov>; Letendre, Daisy
<letendre.daisy@epa.gov>; Sharpe, Kristinn
<Sharpe.Kristinn@epa.gov>; janet collins
<jcollins@croplifeamerica.org>; Jay Vroom
<JVroom@croplifeamerica.org>; Allison Jones (allisonjones@naicc.org)
<allisonjones@naicc.org>
Subject: Importance of the GLP Audit and Inspection Program

Ms. Bodine:

On behalf of Crop Life America (CLA) and the National Association of Independent Crop Consultants (NAICC), we want to follow up the CLA visit with you on May 10 with more detail on the importance of the Good Laboratory Practice (GLP) Audit and Inspection program to the crop protection industry. We would welcome the opportunity to continue this conversation. I am taking the liberty of copying other EPA leaders with a stake in this program.

- We are concerned about a loss of vision within the management at the Environmental Protection Agency (EPA) regarding what the GLP program should do and be and accomplish.
- The GLP inspection and audit program is being starved of resources and personnel. In 1994, when the program was under the Office of Prevention, Pesticides, and Toxic Substances (OPPTS), there were 19 inspectors, 6 support staff, and a contractor supporting the GLP program. Currently in the Office of Enforcement and Compliance Assurance (OECA) there are 4 inspectors and no support staff.
- A reasonable frequency of audit and inspection of the individual labs and facilities is necessary to assure EPA of the quality and integrity of the data supporting pesticide product registrations, as required by law, regulation, and international agreement.
- There are some 1400 laboratories, facilities, and field sites in the US participating in GLP research on pesticides. With current staffing of the audit and inspection program, keeping up with that number of facilities seems like an impossible task.
- By comparison, the burden of other GLP audit and inspection programs is more balanced, for example: US-FDA (300 labs, 75 inspectors); Canada (40 labs, 23 inspectors); UK (100 labs, 8 inspectors); Germany (160 labs, 53 inspectors). Many of these inspectors in other programs are part time.
- If inspections are not conducted with sufficient frequency, registrants may feel obligated to take their research to foreign contract research organizations (CROs), leading to loss of business for US laboratories.

- The US is obligated as a member of the Organization for Economic Cooperation and Development (OECD) to comply with requirements of formal OECD Decisions regarding GLP and audits and inspections. This has a direct bearing on the ability of US industry to operate internationally. Among other things, these requirements cover:
    - The nature and frequency of audits and inspections;
    - Providing statements of such audits and inspections to foreign governments in a timely manner.
- Historically, US has had a preeminent role in the development and management of the GLP and Mutual Acceptance of Data (MAD) programs under OECD. In recent years, EPA participation in the OECD GLP Committee and other international forums has been curtailed, resulting in loss of leadership, where the US should be in the forefront. The US should maintain active engagement in moulding and shaping the future direction of MAD.
- Because the EPA does not issue compliance certificates to GLP facilities, the inspection closure letters from EPA are vital in the registration submission process to many other countries, to assure studies have been conducted in a GLP-compliant facility. Lack of the closure letter creates a significant barrier to acceptance of US studies by other countries.
- Registrants experience delays in registrations when they have to obtain a closure letter from the laboratory to send to the monitoring authority in the foreign government. The current practice is to obtain the closure letter in advance to include with the study report in the registration application, and not wait for the monitoring authority to make a request.
- New CROs have a hard time breaking into the business, because of lack of inspections and lack of the ability to be inspected.
- The industry – both registrants and CROs – have a great deal of confidence in and respect for Francis Liem who has led the audit and inspection effort for many years. The Agency must maintain this level of experience and expertise.
- Interaction of audit and inspection staff with industry has been curtailed. We depend on frequent interaction with them in meetings and conferences to keep up to date on the latest developments in GLP.
- The prospect of additional funding authorized by the Pesticide Registration Improvement Act (PRIA) to bolster the GLP program is heartening. It is the clear intent of PRIA legislation that this additional funding supplement, and not replace, current funding from appropriations. It is essential that the new funds set aside for this purpose be spent exclusively on the GLP program.
- In 2016 there was serious consideration of moving the audit and inspection program to the Office of Chemical Safety and Pollution Prevention (OCSPP). We felt then and still feel now that this would be a very positive step for the program.
    - The GLP program began in OPPTS {now known as OCSPP), and was located there until the mid 1990s.

- The principle purpose of EPA's GLP program is to support the registration decisions made by the Office of Pesticide Programs (OPP) within OCSPP.
- With such an organizational change, the GLP program could be more responsive to the audit and inspection needs of OPP for specific studies and facilities.
- Administration of funds from product maintenance fees under PRIA for the GLP program would be simpler and more straightforward in OCSPP, which administers all other PRIA funds.
- The GLP program does not audit or inspect research performed by OPP, so the organizational connection would not represent a conflict of interest.
- OCSPP can maintain the appropriate organizational structure to assure independence of the GLP program.

- A robust GLP program in full compliance with the OECD MAD requirements demonstrates to all stakeholders the integrity of industry-supported and generated data that underpin pesticide registrations in the US and around the world. The EPA has a significant responsibility to vigorously defend its Pesticide Programs, and the GLP program should contribute in that regard.

Ray S. McAllister, Ph.D.

Senior Director, Regulatory Policy

CropLife America

202-872-3874 (office)

202-577-6657 (mobile)

ray@croplife.us

Allison Jones

Executive Vice President

National Alliance of Independent Crop Consultants (NAICC)

901.861.0511

AllisonJones@NAICC.org

CC:

Larry Starfield, Principal Deputy Assistant Administrator, OECA

Jeff Morris, Director, OPPT; chief US Head of Delegation to OECD on Chemicals

Nancy Beck, Acting Assistant Administrator, OSCPP

Louise Wise, Deputy Assistant Administrator, OSCPP

Rick Keigwin, Director, OPP

Ed Messina, Acting Deputy Director, OPP

Daisy Letendre, Smart Sectors Program

Kristinn Sharp, Smart Sectors Program